REMARKS

Claims 17, 19, 34, and 51 were previously canceled. No amendments have been made herein. Claims 1-16, 18, 20-33, and 35-50 are pending; although, claims 18, 20-33 and 35-50 have been withdrawn from consideration.

Regarding the Information Disclosure Statement

Applicants acknowledge that the Examiner has indicated that the documents mentioned in the body of the IDS filed April 7, 2009, and Appendix A attached thereto have been considered.

Regarding the Restriction Requirement

The Examiner stated that the Restriction Requirement was still deemed proper because "the composition disclosed of instant claim 1 is not novel." Applicants are confused because Claim 1 is a method claim, not a composition claim. Thus, there is no "composition disclosed of instant claim 1." Besides, even if one assumes that the compositions are not novel, that fact would not relate to the special technical feature in the methods used to make the composition.

It seems from the initial Restriction Requirement and the Examiner's final conclusions about Applicants' arguments in response to same, that the Examiner is wrongly viewing the current claims as composition claims. Specifically, the Examiner lodged the Restriction Requirement by asserting that the "compositions" didn't share a common technical feature. In response, Applicants canceled all composition claims, leaving only method claims. Applicants then pointed out the Examiner's error in characterizing the special technical feature of the claims as merely a composition that contained active, polymer, and salt. Now, in the current Office Action, the Examiner responds to Applicants' arguments by noting that organic ion and organic salt are of the same scope. That point seems to relate to composition, which again suggests that the Examiner is confusing a method claim with a composition claim. At the very least, it is unclear how such a statement relates to the Restriction Requirement, let alone rebuts Applicants' argument about the special technical feature of the method.

All of the claims recite methods that have an organic ion (organic salt) in the aqueous phase and the active and polymer in the organic phase. There is therefore a common technical feature recited in the claims.

Rule 1.144, Petition from requirement for restriction, provides that:

> After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181).

Applicants have previously, and do so again here, request that the Restriction Requirement be reconsidered. Applicants have elected to defer to petition the restriction holding until after final action or allowance of the elected claims (*i.e.*, claims 1-16).

Rejections under 35 U.S.C. § 102

The Examiner rejected claims 1, 4-5, 7, and 9-16 under 35 U.S.C. § 102(b) as allegedly being anticipated by Okada (U.S. Patent 5,814,342) as evidenced by Franssen *et al.* Applicants respectfully submit that this rejection is improper.

The Examiner alleged that the subject matter of claim 5 in Okada read on Applicants claims. Specifically, the Examiner stated that "Okada teaches . . . in claim 5 a process for preparing a microcapsule exhibiting zero order release of a LH-RH analog, wherein said LH-RH analog is the bioactive agent." The Examiner went on to say that "when Okada claim 5 is read in light of column 4, lines 62-66, it is evident that the aqueous phase of claim 5 may further comprise an organic ion for the purposes of maintaining the stability of the physiologically active peptide." The continued reliance on claim 5 in Okada is repeated throughout the rejection. (See the specific reasons for rejecting the dependent claims on pages 8 and 9 of the Office Action; they all rely on "Okada claim 5.") When the Examiner cited other sections of Okada in the rejection it was done to expand upon certain words/phrases from claim 5 in Okada. Thus, it is clear that the rejection is based on the allegation that claim 5 in Okada reads on the claims of the present application, and this is therefore an improper rejection.

In *In re Benno* (1985), 768 F.2d 1340, (Fed. Cir. 1985), the Federal Circuit held that it was error for the U.S. Patent and Trademark Office to reject a claim in a patent application merely because the subject matter of that claim fell within the broadly-worded claim of a prior art patent. The court explained:

> The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses only that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding. While it is true ... that "a claim is part of the disclosure," that point is of significance principally in the situation where a patent application as filed contains a claim which specifically

> discloses something not disclosed in the descriptive part of the specification (claims being technically part of the "specification," 35 USC 112, 2d par.), in which case the applicant may amend the specification without being charged with adding "new matter," within the meaning of § 132. ... But that is not the situation here. [The claim of the prior art patent] does not disclose any structure additional to what the ... specification discloses.

Claim 5 in Okada is a broadly worded claim that cannot be used, as the Examiner does here, to reject Applicants claims. Because the present rejection relied on claim 5 in Okada, the rejection is improper and must be withdrawn.

In addition, even if it were proper to reject Applicants' claims based on claim 5 in Okada (which it is not), Okada still does not anticipate the present claims. Specifically, the Examiner stated that Applicants' claim 1 was anticipated because the aqueous phase of Okada claim 5, read in light of column 4, lines 62-66, "may further comprise an organic ion for the purposes of maintaining stability of the physiologically active peptide" (*see* Office Action at page 7). But even if this were true and the aqueous phase of Okada claim 5 did contain an organic ion, it would still not result in a process that anticipated Applicants' claim 1.

Claim 1 recites "combining an organic phase comprising a bioactive agent and a polymer with an aqueous phase comprising an organic ion." Thus, the active and polymer are together in the organic phase. Okada, whether in claim 5 or elsewhere, teaches that the active is in the aqueous phase, not together with the polymer in the organic phase. *See* column 1, line 65, to column 2, line 9, which states that the process involves an inner aqueous phase containing the polypeptide (*i.e.*, active) and an oil phase containing the polymer. This process is referred to again and again in Okada (*see* col. 3, ll. 22-23 and 64; col. 4, ll. 55-61; col. 5, ll. 8-10; and Examples 1-4). Thus, Okada only teaches a method where the active is in the aqueous phase and the polymer is in the organic phase. The following table is provided to help further illustrate this difference.

	Claim 1	Okada
Organic phase	Polymer Active	Polymer
Aqueous phase	Organic ion	Active (optional organic ion)

Because the Applicants' claims recite a method whereby an organic phase comprising an active and polymer is contacted with an aqueous phase comprising an organic ion, and Okada does not disclose an organic phase comprising an active and polymer, the rejection under § 102 in view of Okada must be withdrawn for this additional reason.

Claims 2-16 depend from claim 1 and are therefore not anticipated by Okada for the reasons outlined above. It is also noted that the withdrawn claims likewise recite an organic phase with an active and polymer being added to an aqueous phase containing an organic ion. As such, the withdrawn claims are novel over Okada as well.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 2-3 and 6 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Okada in view of Lyons (U.S. Patent 6,194,006). Specifically, the Examiner alleged that Okada fails to teach certain features recited in the claims (*e.g.*, specific preservatives, cosolvents, amounts of emulsifying agents). For these missing features, the Examiner relied on Lyons. Applicants respectfully traverse this rejection.

Even if one were to combine the particular preservatives, cosolvents, and amounts of emulsifying agents from Lyons with the method of Okada, the resulting method would not be as recited in Applicants' claims. As noted above, Okada fails to teach a method whereby the active is present with the polymer in the organic phase, and then the organic phase is contacted with an aqueous phase comprising an organic ion. Combining the specific components from Lyons into the method of Okada, as the Examiner contended, would not fix this deficiency. Nothing in either Okada or Lyons teaches a method whereby the active and polymer are in the organic phase and an organic ion is in the aqueous phase. Thus, the Examiner has failed to make a *prima facie* case of obviousness because the combination of Okada with Lyons does not result in the presently claimed methods.

Moreover, the Examiner's attention is drawn to Example 3 of the Applicants' specification where the methods as claimed are exemplified. It was found that the use of an organic ion in the aqueous phase, and the active and polymer in the organic phase, eliminated the need to form a complex species of a water-soluble active in an independent step (in other words, eliminating the need to have the active together with the ion, and also with the polymer in the organic phase). It also allowed for greater loading. In Table 6, from the claimed method, the loading was from about 5 to about 17.5%. But in Tables 1-5, from methods where the polymer,

active, and ion were all in the organic phase, the maximum loading was 8%, with the averages ranging from 2-6%. See also paragraph 0119. Still further, the amount of active release is lower when one uses a method where the active, ion, and polymer are all in the organic phase, as compared to the claimed method where the ion is in the aqueous phase (compare Table 2 with Table 6). Accordingly, the claimed methods result in compositions with more desirable properties (e.g., loading and amount released) that other methods. As such having the organic ion in the aqueous phase and the active and polymer in the organic phase is not merely a routine optimization. The advantages of the claimed method are real, have been demonstrated and described in the application, and were certainly not taught or suggested by Okada or Lyons.

In light of the above, withdrawal of the rejection under 35 U.S.C. 103 is respectfully requested.

Rejections under 35 U.S. C. § 112

The Examiner rejected claims 6 and 8 under 35 U.S.C. § 112, 2nd ¶, as allegedly being indefinite for the use of the term "about" in connection with numerical ranges. In making this rejection, the Examiner correctly noted (citing appropriate case law and sections of the MPEP) that the use of the term "about" is appropriate and can be definite in many cases. However, the Examiner concluded that because Beaurline et al. (U.S. Patent 5,112,604) taught a range of preservative that was close to the ranges recited in claims 6 and 8, the term "about" in these claims was indefinite.

Beaurline is not "close" to the claims because it does not disclose a method like that recited in base claim 1. Thus, contrary to the Examiner's conclusions, Beaurline is not an otherwise identical prior art method that requires exact specificity around the ranges in claims 6 and 8 in order for the skilled artisan to be able to distinguish the claims. As such, withdrawal of this rejection is respectfully requested.

CONCLUSION

Enclosed herewith is payment in the amount of $1,290.00, which includes the $1,110.00 fee under 37.C.F.R. §1.17(a)(3) for the Three-Month Extension of Time and the $180.00 fee under 37.C.F.R. §1.17(p) for the Supplemental Information Disclosure Statement. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF EFS-WEB SUBMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included is being submitted electronically via EFS-WEB submission, on the date indicated below.

/Christopher L. Curfman/	October 13, 2009
Christopher L. Curfman	Date